

## **REMARKS**

### **Status of Claims**

Claims 23 - 26 and 28 -47 remain pending in the application. Claims 23, 33 and 43 are amended to correct minor errors as to form. The Examiner's withdrawal of prior art rejections is gratefully acknowledged.

### **Rejections under 35 USC §112, first paragraph**

In the interests of advancing prosecution, all independent claims had been previously amended to recite filtration through a filter series comprising "a glass filter and a nylon filter" in lieu of the prior claimed "at least one glass filter and at least one nylon filter." However, the claims remain comprising claims and as amended are meant to fully embrace infringement through the use of more than one glass fiber and/or more than one nylon filter.

The examiner has now given a new matter rejection on the asserted basis that the specification as filed only discloses the use of 0.2µM glass fiber and nylon filters and that there is no disclosure of the use of any size glass fiber or nylon filters for the removal of endotoxins. This new matter rejection is surprising in light of the fact that claims to glass fiber and nylon filters without size limitations have been pending since 08-23-2003 (see claims 27 and 28) and yet this is the first time a new matter rejection on this asserted written description basis has appeared. Nonetheless, the Examiner's close attention to any potential written description issues is appreciated as well as the present opportunity to traverse the rejection.

To any extent that the examiner does not find support for glass or nylon filters of any size other than 0.2µM, the examiner's attention is drawn to explicit support on the original application on page 13, lines 24-32, and corresponding [0058] of the published application 2002/0198372 where it is recited that:

Filtration through 0.2 µm filters, from certain vendors, can be used to remove endotoxin as well as microorganisms, while resulting in minimal nucleic acid loss. 0.2 µm filters are available from a variety of commercial sources including, e.g., Pall-Filtron (East Hills, N.Y.), Sartorius (Edgewood, N.Y.), and Gelman (Ann Arbor, Mich.). **Ideally, the filter used will be one that binds endotoxin while allowing nucleic acid to pass through.** Pall Ultipor N<sub>66</sub> filters and Sartorius Sartopure GF filters have been found to remove substantial endotoxin

with high yield of nucleic acid. Preferably, the nucleic acid solution is pre-filtered through a nominal **0.2  $\mu\text{m}$  or a 0.45  $\mu\text{m}$**  or larger filter before filtration through an absolute 0.2  $\mu\text{m}$  filter. Glass and nylon filters are preferred. Filters made for the removal of endotoxin, e.g., ion exchange filters, in many cases are not suitable for use with nucleic acid purification because the nucleic acid will bind to the filter. (*emphasis added*).

Thus, the applicant disclosed not only **0.2  $\mu\text{m}$  filters but also 0.45  $\mu\text{m}$  filters**. Furthermore, the Applicants taught the relevant size characteristic need only be a glass and nylon filter that “binds endotoxin while allowing nucleic acids to pass through.” Applicants respectfully but firmly argue that, to one of skill in the art, the disclosure evinces possession at the time of filing of a process of plasmid purification using glass and nylon filters that are important to removal of endotoxins on the basis of their identified chemical characteristics, i.e. glass and nylon, not their physical dimensions. Furthermore, the disclosure literally teaches such filters having at least a two fold size range.

As previously explained, the presently claimed invention involves a specific combination for purification of plasmid containing solutions by filtration through a series of specific steps and including specific media including glass fiber and nylon filtration. The claimed glass fiber and nylon filters are not functioning merely as inert screens for debris and contaminants but are further removing endotoxins by binding to the charged glass fiber and nylon supports. Applicants disclosure of their preferred embodiments of 0.2  $\mu\text{m}$  filters, **as well as 0.45  $\mu\text{m}$  filters**, should not serve as a basis for requirement to a specific size. Such a requirement would arguably work to deny the inventors protection over the substance of their invention while arguably permitting third parties to evade the literal scope of the claims by the simple expedient of utilizing a non-essential feature.

### **Conclusion**

For the reasons stated herein, the Applicant respectfully submits that independent claims 23, 33, 37 and 43 are allowable and that the dependent claims are, in turn, also allowable. Applicant respectfully requests allowance of the claims at an early date. The Commissioner is authorized to charge any additional fees incurred in this application or credit any overpayment to Deposit Account No. 50-1922. Should the Examiner have any questions, please do not hesitate to call Applicant's attorney at 832-446-2421.

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Respectfully submitted,

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